

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it carries a valid OMB control number.				Complete if Known	
Substitute for form 1449/PTO				Application Number	10/542,958
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Filing Date	January 23, 2004 (I.A.)
<i>(Use as many sheets as necessary)</i>				First Named Inventor	William R. Jacobs, Jr.
				Art Unit	not yet determined
				Examiner Name	not yet determined
Sheet	1	of	1	Attorney Docket Number	96700/1031

[illegible]

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	4	WO 03/070164 A2	08-28-2003	Jacobs, Jr. et al.		

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/542,958
				Filing Date	January 23, 2004 (I.A.)
				First Named Inventor	William R. Jacobs, Jr.
				Art Unit	not yet determined
				Examiner Name	not yet determined
Sheet	2	of	5	Attorney Docket Number	96700/1031

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	5	ANDERSEN, P., "Host Responses and Antigens Involved in Protective Immunity to Mycobacterium tuberculosis"; Scand. J. Immunol. 1997, pp.115-31, Vol. 45.	
	6	ANDERSEN, P., et al., "Proteins Released from Mycobacterium tuberculosis during Growth"; Infection and Immunity, June 1991, pp. 1905-10, Vol. 59, No. 6.	
	7	BEHR, M.A., et al., "Comparative Genomics of BCG Vaccines by Whole-Genome DNA Microarray"; Science, May 28, 1999, pp. 1520-23, Vol. 284.	
	8	CAMACHO, L.R., et al., "Identification of a virulence gene cluster of Mycobacterium tuberculosis by signature-tagged transposon mutagenesis"; Molecular Microbiology, 1999, pp. 257-67, Vol. 34.	
	9	CHAMBERS, M.A., et al., "Identification of a Mycobacterium bovis BCG Auxotrophic Mutant That Protects Guinea Pigs against M. bovis and Hematogenous Spread of Mycobacterium tuberculosis without Sensitization to Tuberculin"; Infection and Immunity, Dec. 2000, pp. 7094-99, Vol. 68, No. 12.	
	10	COLE, S.T., et al., "Deciphering the biology of Mycobacterium tuberculosis from the complete genome sequence"; Nature, June 11, 1998, pp. 537-44 + table pages, Vol. 393.	
	11	COX, J., et al., "Complex lipid determines tissue-specific replication of Mycobacterium tuberculosis in mice"; Nature, Nov. 4, 1999, pp. 79-83, Vol. 402.	
	12	DASCHER C.C. et al., "Immunization with a mycobacterial lipid vaccine improves pulmonary pathology in the guinea pig model of tuberculosis"; International Immunology, Aug. 2003, pp. 915-25, Vol. 15, No. 8.	
	13	DE VOSS, J.J., et al. "The salicylate-derived mycobactin siderophores of Mycobacterium tuberculosis are essential for growth in macrophages"; PNAS, Feb. 1, 2000, pp. 1252-57, Vol. 97, No. 3.	
	14	GLICKMAN, M.S., et al., "The Mycobacterium tuberculosis cmaA2 Gene Encodes a Mycolic Acid trans-Cyclopropane Synthetase"; The Journal of Biological Chemistry, Jan. 19, 2001, pp. 2228-33, Vol. 276, No. 3.	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>		Complete if Known			
		Application Number	10/542,958		
		Filing Date	January 23, 2004 (I.A.)		
		First Named Inventor	William R. Jacobs, Jr.		
		Art Unit	not yet determined		
		Examiner Name	not yet determined		
Sheet	3	of	5	Attorney Docket Number	96700/1031

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	15	GORDON, S.V., et al., "Genomics of Mycobacterium bovis"; Tuberculosis, 2001, pp. 157-63, Vol. 81(1/2).	
	16	GULERIA, I., et al., "Auxotrophic vaccines for tuberculosis"; Nature Medicine, March 1996, pp. 334-37, Vol. 2, No. 3.	
	17	HARBOE M. et al., "Evidence for Occurance of the ESAT-6 Protein in Mycobacterium tuberculosis and Virulent Mycobacterium bovis and for Its Absence in Mycobacterium bovis BCG"; Infection and Immunity, Jan. 1996, pp 16-22, Vol. 64, No. 1.	
	18	HERNANDEZ-PANDO R. et al., "Pathogenesis of Tuberculosis in Mice Exposed to Low and High Doses of an Environmental Mycobacterial Saprophyte before Infection"; Infection and Immunity, Aug. 1997, pp. 3317-27, Vol. 65, No. 8.	
	19	HONDALUS, M.K., et al., "Attenuation of and Protection Induced by a Leucine Auxotroph of Mycobacterium tuberculosis"; Infection and Immunity, May 2000, pp. 2888-98, Vol. 68, No. 5.	
	20	HSU, T., et al., "The primary mechanism of attenuation of bacillus Calmette-Guérin is a loss of secreted lytic function required for invasion of lung interstitial tissue"; PNAS, October 2003, pp. 1240-25, Vol. 100, No. 21.	
	21	JACKSON, M., et al., "Persistence and Protective Efficacy of a Mycobacterium tuberculosis Auxotroph Vaccine"; Infection and Immunity, June 1999, pp. 2867-73, Vol. 67, No. 6.	
	22	LADEL, C.H., et al., "Immune response to Mycobacterium bovis bacille Calmette Guérin infection in major histocompatibility complex class I- and II-deficient knock-out mice: contribution of CD4 and CD8 T cells to acquired resistance"; Eur. J. Immunol., 1995, pp. 377-384, Vol. 25.	
	23	MAHAIRAS, G.G., et al., "Molecular Analysis of Genetic Differences between Mycobacterium bovis BCG and Virulent M. bovis"; Journal of Bacteriology, March 1996, pp. 1274-82, Vol. 178, No. 5.	
	24	MANCA, C., et al., "Virulence of a Mycobacterium tuberculosis clinical isolate in mice is determined by failure to induce Th1 type immunity and is associated with induction of IFN-alpha/beta"; PNAS, May 8, 2001, pp. 5752-57, Vol. 98, No. 10.	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Complete if Known			
		Application Number	10/542,958		
		Filing Date	January 23, 2004 (I.A.)		
		First Named Inventor	William R. Jacobs, Jr.		
		Art Unit	not yet determined		
		Examiner Name	not yet determined		
Sheet	4	of	5	Attorney Docket Number	96700/1031

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	25	MCKINNEY, J.D., et al., "Persistence of Mycobacterium tuberculosis in macrophages and mice requires the glyoxylate shunt enzyme isocitrate lyase"; Nature, Aug. 17, 2000, pp. 735-38, Vol. 406	
	26	MOGUES, T., et al., "The Relative Importance of T Cell Subsets in Immunity and Immunopathology of Airborn Mycobacterium tuberculosis Infection in Mice"; J. Exp. Med., Feb. 2001, pp. 271-280, Vol. 193, No. 3.	
	27	MOREIRA A.L. et al., "Mycobacterial Antigens Exacerbate Disease Manifestations in Mycobacterium tuberculosis-Infected Mice"; Infection and Immunity, Apr. 2002, pp 2100-07, Vol. 70, No. 4.	
	28	PAVELKA, JR., M.S. and JACOBS, JR., W.R., "Comparison of the Construction of Unmarked Deletion Mutations in Mycobacterium smegmatis, Mycobacterium bovis, Bacillus Calmette-Guerin, and Mycobacterium tuberculosis H37Rv by Allelic Exchange", Journal of Bacteriology, Aug. 1999, pp. 4780-89, Vol. 181, No. 16.	
	29	SAMBANDAMURTHY V.K. et al., "A pantothenate auxotroph of Mycobacterium tuberculosis is highly attenuated and protects mice against tuberculosis"; Nature Medicine, Oct. 2002, pp. 1171-74, Vol. 8, No. 10.	
	30	SAMBANDAMURTHY V.K. et al., "Long-Term Protection against Tuberculosis following Vaccination with a Severely Attenuated Double Lysine and Pantothenate Auxotroph of Mycobacterium tuberculosis"; Infection and Immunity, Feb. 2005, pp. 1196-203, Vol. 73, No. 2.	
	31	SAMPSON S.L. et al., "Protection Elicited by a Double Leucine and Pantothenate Auxotroph of Mycobacterium tuberculosis in Guinea Pigs"; Infection and Immunity, May 2004, pp. 3031-37, Vol. 72, No. 5.	
	32	SKINNER M.A. et al., "A DNA prime-live vaccine boost strategy in mice can augment IFN-gamma responses to mycobacterial antigens but does not increase the protective efficacy of two attenuated strains of Mycobacterium bovis against bovine tuberculosis"; Immunology, Apr. 2003, pp. 548-55, Vol. 108, No. 4.	
	33	SLYSHENKOV, V.S., et al., "Pantothenic Acid and Its Derivatives Protect Ehrlich Ascites Tumor Cells Against Lipid Peroxidation"; Free Radical Biology & Medicine, 1995, pp. 767-72, Vol. 19, No. 6.	
	34	SMITH, D.A., et al. "Characterization of Auxotrophic Mutants of Mycobacterium tuberculosis and Their Potential as Vaccine Candidates"; Infection and Immunity, Feb. 2001, pp. 1142-50, Vol. 69, No. 2.	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/542,958
				Filing Date	January 23, 2004 (I.A.)
				First Named Inventor	William R. Jacobs, Jr.
				Art Unit	not yet determined
				Examiner Name	not yet determined
Sheet	5	of	5	Attorney Docket Number	96700/1031

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	35	TAYLOR, J.L., et al., "Pulmonary Necrosis Resulting from DNA Vaccination against Tuberculosis"; Infection and Immunity, Apr. 2003, pp. 2192-98, Vol. 71, No. 4.	
	36	WEBER, I., et al., "Anaerobic nitrate reductase (narGHJI) activity of Mycobacterium bovis BCG in vitro and its contribution to virulence in immunodeficient mice"; Molecular Microbiology, 2000, pp. 1017-25, Vol. 35, No. 5.	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.